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## Attaining Subsidiarity-Based Multilevel Governance of Genetically Modified Cultivation?

Mary Dobbs

### ABSTRACT

*The cultivation of genetically modified (GM) crops in the EU is highly harmonised, but with persisting conflicts over authority. The Commission responded to internal and external pressures with a more flexible approach to coexistence, a proposed opt-out clause and a promise to review the existing EU GM regime, providing an opportunity to consider and suggest paths of development. This article considers the post-authorisation policy-making powers of Member States and subnational regions, in light of subsidiarity-based multilevel governance. It considers the different approaches to risk-centred issues and more general policy choices. Overall, the developments occurring at the EU level are strengthening subsidiarity-based multilevel governance within the GM cultivation regime, but with significant opportunities to improve it further through focussing on the complementary powers, coordination and the regional levels in particular.*

Keywords: genetically modified organisms; multilevel governance; subsidiarity.

### 1. INTRODUCTION

This article addresses the highly contentious issue of the allocation of policy-making powers regarding genetically modified (GM) cultivation. It provides an initial foray into determining where these powers *ought* to lie, in light of subsidiarity-based multilevel governance, and whether the current European Union (EU) regime achieves this effectively in relation to post-authorisation powers. This is, to say the least, a bold endeavour and what follows is not proffered as a panacea for governing GM crops – the very contention and complexity that increases the importance of attempting to develop a normative approach also means that no simple solution is available. The intention is simply to steer the debate in new directions and provide a focus point for considering where powers should lie in principle.

It does so because of the on-going conflict within the EU over these powers, the constant stalemates and the tweaks and adjustments that occur in a reactionary manner. Thus, in a supposedly highly-harmonised regime, Member States have called for further powers to limit or exclude cultivation within their territories<sup>1</sup> and subnational regions have established a network of GM-free regions.<sup>2</sup> Only MON810 is currently authorised for cultivation in the EU and national bans persist, despite the Commission's belief that they are in breach of EU law.<sup>3</sup> France even re-introduced a

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<sup>1</sup> E.g. note submitted by Austrian Delegation, *Genetically Modified Organisms – A Way Forward* (25 June 2009): <http://register.consilium.europa.eu/pdf/en/09/st11/st11226-re01.en09.pdf>.

<sup>2</sup> E.g. map dated September 2012: <http://www.gmo-free-regions.org/gmo-free-regions/maps.html>; 'Charter of the Regions and Local Authorities of Europe on the Subject of Coexistence of Genetically Modified Crops with Traditional and Organic Farming' (Florence, 2005).

<sup>3</sup> Commission Communication on the freedom for Member States to decide on the cultivation of genetically modified crops COM(2010) 380 final, fn 4.

national ban on the cultivation of GM maize,<sup>4</sup> despite its own *Conseil d'Etat* previously striking down a similar ban on the basis of EU law,<sup>5</sup> and Hungary amended its Constitution in 2011 to prohibit GM cultivation.

As a result of these internal pressures, along with external pressures from sources such as the World Trade Organisation (WTO),<sup>6</sup> the Commission instigated a number of compromises to the regime. These include the 2010 Cultivation Package, with its more flexible approach to coexistence measures<sup>7</sup> and proposed 'opt-out' clause for Member States.<sup>8</sup> Directive 2015/412<sup>9</sup> enacted a revised version of this opt-out, which enables Member States to request or potentially impose geographical restrictions on GM cultivation within their territories. Together these provide a degree of decentralisation in what was an area of maximum harmonisation and may temporarily appease the Member States and regions. However, it is questionable whether even these substantial changes will ultimately resolve the battle over authority, or whether they will just act as a temporary patch. In the long run, a more proactive approach may be required – one that considers specifically where relevant powers *ought* to rest.

A significant challenge in this task is that the regions, Member States and EU all have vested interests in GM cultivation, which overlap and conflict, due to its multisectoral and multilevel nature.<sup>10</sup> There is no singular ideal or obvious location to situate policy-making powers. Yet, this very challenge highlights a potential starting point – that of multilevel governance – as it may be necessary to fragment authority across the levels.<sup>11</sup> However, multilevel governance alone cannot suffice for our purposes, as it lacks a normative value.

This article builds upon the existing academic discourse on multilevel governance<sup>12</sup> by applying it conjunction with the broad, interdisciplinary concept of subsidiarity – thereby developing a normative framework with which to analyse GM cultivation and the allocation of powers (Section 2). It considers the appropriate levels for various

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<sup>4</sup> *Loi n° 2014-567 du 2 juin 2014 relative à l'interdiction de la mise en culture des variétés de maïs génétiquement modifié.*

<sup>5</sup> Arrêté of the Conseil d'Etat, *Association générale des producteurs de maïs (AGPM) et autres*, 1 August 2013.

<sup>6</sup> E.g. F Randour, C Janssens and T Delreux, 'The cultivation of genetically modified organisms in the European Union: a necessary trade-off?' (2014) 52 J.Com.Mar.St. 1.

<sup>7</sup> Commission Recommendation on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops, [2010] OJ C200/1.

<sup>8</sup> *Proposal for a Regulation amending Directive 2001/18/EC as Regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of GMOs in their Territory* COM(2010)375.

<sup>9</sup> Directive 2015/412/EU of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory, [2015] OJ L68/1.

<sup>10</sup> E.g. GC Shaffer and MA Pollack, 'The EU Regulatory System for GMOs' in M Everson and E Vos (eds), *Uncertain Risks Regulated: Facing the Unknown in National, EU and International Law*, (Routledge-Cavendish 2008). See Section 3 below.

<sup>11</sup> M Lee, 'The Ambiguity of Multi-Level Governance and (De-)Harmonisation in EU Environmental Law' (2012) 15 CYELS 357, 358.

<sup>12</sup> E.g. Shaffer and MA Pollack (n10); Randour, Janssens and Delreux (n6); M Lee, 'Multi-level Governance of Genetically Modified Organisms in the European Union: Ambiguity and Hierarchy' in L Bodiguel and MN Cardwell (eds), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, (OUP, 2010); and M Weimer, 'The Right to Adopt Post-Market Restrictions of Genetically Modified Crops in the EU - A Shift from De-Centralised Multi-Level to Centralised Governance in the Case of GM Foods' (2012) 3 EJRR 445.

policy-making powers regarding GM cultivation in light of subsidiarity-based multilevel governance (Section 3). It proceeds to analyse the key post-authorisation roles left for Member States and subnational regions in the EU GM cultivation regime (Section 4). The resulting analysis necessarily remains relatively broad-stroke and more nuanced approaches may be required in practice, but nonetheless some important initial conclusions can be drawn.

It is argued that subsidiarity-based multilevel governance calls for the core policy-making powers regarding environmental and health risks to be located at the EU level, but with important complementary policy-making powers to be located at the national and regional levels. In contrast, it is argued that the opposite approach should be taken to policy-making powers not directly related to risk, but with controls still in place to protect the internal market. Further, it is argued that substantial coordination is required, in light of the complicated mishmash of powers and the nature of GM cultivation.

Overall, the discussion below indicates that the regime is developing towards the powers resting at the appropriate *loci*. This is especially due to the partial de-harmonisation that has occurred since 2010, whereby environmental and health aspects remain harmonised but a range of other post-authorisation powers have been relocated with the Member States. However, significant challenges remain regarding the extremely limited complementary powers regarding risk, the heavy reliance of regional bodies on their Member States and the lack of broad coordination regarding cultivation.

However, before any such arguments can be developed, it is necessary to consider what the concepts of multilevel governance and subsidiarity entail and how they can assist in this task.

## 2. MULTILEVEL GOVERNANCE THROUGH THE LENS OF SUBSIDIARITY

Multilevel governance recognises the existence of governance at the supranational, national and subnational levels, encompassing two aspects. Firstly, it is broader than pure government. The actors governing may be private bodies and the mechanisms may be softer/broader than binding rules, e.g. social dialogue or open methods of coordination.<sup>13</sup> Secondly, and the focus herein, the governance occurs at various levels, e.g. local, regional, national, transnational and/or international, rather than the traditional national or state-centric focus.<sup>14</sup> Therefore, the various levels have implementing powers, but also discrete policy-making powers regarding aspects traditionally determined by the nation-state.<sup>15</sup> Whilst national executives remain of vital significance, they no longer monopolise policy-making. Simply, it implies the ‘reallocation of authority upwards, downwards and sideways from central states’.<sup>16</sup>

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<sup>13</sup> J Scott and DM Trubek, ‘Mind the Gap: Law and New approaches to Governance in the EU’ (2002) 8 ELJ 1.

<sup>14</sup> E.g. ‘Multi-Level Governance in the EU’, in L Hooghe and G Marks, *Multi-level governance and European integration*, (Rowman & Littlefield, 2001).

<sup>15</sup> Paralleling multilevel regulation, e.g. N Chowdhury and RA Wessel, ‘Conceptualising Multilevel Regulation in the EU: A Legal Translation of Multilevel Governance?’ (2012) 18:3 ELJ 335.

<sup>16</sup> L Hooghe and G Marks, ‘Unraveling the Central State, but How? Types of Multi-level Governance’ (2003) 97(2) APSR 233, 233.

However, multilevel governance traditionally is deployed as a descriptive or analytical tool. To play a normative role, some other concept is required to direct how the powers should be divided and assigned.<sup>17</sup> A useful tool in this respect is the concept of subsidiarity, which provides guidance as to the initial allocation, re-distribution and indeed use of powers in multilevel governance systems – it focuses on ‘the proper geographic distribution of power.’<sup>18</sup>

Subsidiarity is most obviously found in an EU legal context, where it is traditionally applied regarding shared competences and the relationship between the EU and the Member States.<sup>19</sup> Under this (vertical)<sup>20</sup> understanding, it protects the Member States from the EU encroaching excessively upon their powers and could be considered to reflect the general approach of federalism.<sup>21</sup> However, although illustrative, this article is not limited to the legal interpretation of the EU’s principle of subsidiarity.

The concept of subsidiarity is of broader relevance and application.<sup>22</sup> Whether one considers an economic version or the historical Catholic version,<sup>23</sup> or an amalgamation of these, subsidiarity moves away from the (federalist) vision of power held at merely two tiers.<sup>24</sup> Even Article 5(3) TEU now provides that: ‘the Union shall only act if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central *or at regional and local level*, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level’ (emphasis added). Furthermore, subsidiarity indicates that ‘higher levels must not replace the lower ones, but help them... via active intervention and support, when the lower institutions alone are not able to guarantee the adequate continuation of the social purpose in question [or] by guaranteeing, and respecting, the autonomy of lower-level organisations whenever they are capable of achieving the given purpose.’<sup>25</sup>

Subsidiarity, for the purpose of initially allocating powers, therefore focuses on lower levels that are closer to the populace<sup>26</sup> – but with the possibility that it might be appropriate to relocate these powers upwards, where for example the lower levels are ineffective. Hence, a general understanding of subsidiarity calls for powers to be

<sup>17</sup> W Vandenbruwaene, ‘Multi-level Governance Through a Constitutional Prism’ (2014) 2 MJECL 229, 229.

<sup>18</sup> M Landy and SM Teles, ‘Beyond Devolution: From subsidiarity to mutuality’ in K Nicolaidis and R Howse (eds), *The Federal Vision: Legitimacy and Levels of Governance in the United States and the European Union* (OUP, 2001), 414.

<sup>19</sup> E.g. A Estella, *The EU Principle of Subsidiarity and its Critique*, (OUP, 2002), 91.

<sup>20</sup> Cf. horizontal subsidiarity: A Colombo, ‘Principle of Subsidiarity and Lombard: theoretical background and empirical implementation’ in A Colombo (ed), *Subsidiarity governance: theoretical and empirical models*, (Palgrave MacMillan, 2012), 5-6.

<sup>21</sup> E.g. RK Vischer, ‘Subsidiarity as a Principle of Governance: Beyond Devolution’ (2001-2) 35 *Indiana Law Review* 103, 126.

<sup>22</sup> Commission, ‘European Governance-A White Paper’, COM(2001) 428 final, [2001] OJ C287/1, 8; S Weatherill, ‘The Challenge of the Regional Dimension in the European Union’ in S Weatherill and U Bernitz (eds), *The role of regions and sub-national actors in Europe* (Hart, 2005), 2 states that ‘subsidiarity as a general notion of good practice should doubtless equally apply to the relationships between different tiers of governance *within* the Member States’ (original emphasis).

<sup>23</sup> Vischer (n21).

<sup>24</sup> Y Blank, ‘Federalism, Subsidiarity, and the Role of Local Governments in an Age of Global Multilevel Governance’ (2009) 37 *Fordham Urban Law Journal* 509, 545-6.

<sup>25</sup> Colombo (n20), 6.

<sup>26</sup> Estella (n19), 81, considers that there is a negative bias in favour of lower levels and against integration.



located initially, for instance, at the subnational, then national, supranational (EU) or international level as required.<sup>27</sup>

## 2.1 Legitimacy of subsidiarity-based multilevel governance

However, multilevel governance, whether directed by subsidiarity or otherwise, poses a significant issue regarding sovereignty and legitimacy. Sovereignty and authority claims traditionally focus on the nation-state,<sup>28</sup> as reflected in Westphalian sovereignty and state-centric governance. Thus the EU's multilevel nature, reflected in the 'multiple, intermeshing competences, complementary policy functions and variable lines of authority',<sup>29</sup> challenges the overall authority of the nation-state and, thereby, the legitimacy of the EU regime and legislation.<sup>30</sup> However, if one 'recalibrates'<sup>31</sup> the initial premise of legitimacy away from Westphalian sovereignty, multilevel governance has the potential to support the legitimacy of the resulting approaches and system as a whole.<sup>32</sup> This is especially the case when it is applied in conjunction with subsidiarity with its starting point in decentralisation but with a willingness to be 'upwardly mobile' where appropriate.

If one casts aside the commonly ingrained belief that policy-making powers should rest with the nation-state, decentralisation can be wonderfully logical. Democratically founded nation-states gain their authority typically from 'the will of the people' and thus receive a mandate to represent their people. Yet, even within a nation, the people are rarely homogenous and frequently multiple cultures exist separate from the majority and, in effect, ruling culture. The nation-state may manage the heterogeneity effectively, for instance through dialogue with community representatives. However, voices of minorities can easily be lost and submerged in furtherance of the 'national' approach. Consequently, more localised representation can represent the populace with greater accuracy. It thereby may have a greater legitimacy claim than the higher legislative bodies intended to represent the entire populace, especially where heterogeneity exists.<sup>33</sup> This clearly does not mean that the nation-state should be disbanded or that regions are so distinct that they should necessarily leave the nation-state, but indicates that they at least should have some relevant powers.<sup>34</sup>

Further, the lower the body, the greater their local knowledge and expertise is likely to be, e.g. regarding the cultures, societal values, business interests, traditions, and geographical, environmental and climatic conditions present.<sup>35</sup> Therefore, locals tend

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<sup>27</sup> K Van Kersbergen and B Verbeek, 'Subsidiarity as a Principle of Governance in the European Union' (2004) 2 Comparative European Politics 142, 144.

<sup>28</sup> E.g. F Hinsley, *Sovereignty*, (CUP, 1986), 158.

<sup>29</sup> G Marks, L Hooghe, and K Blank, 'European Integration from the 1980's: State-Centric v Multi-level governance' (1996) 34:3 J.Com.Mar.St. 341, 342.

<sup>30</sup> C Shore, "'European Governance" or Governmentality? The European Commission and the Future of Democratic Governance' (2011) 17 ELJ 287.

<sup>31</sup> Vandenbruwaene (n17), at 237-8.

<sup>32</sup> E.g. C Scott, 'The Governance of the European Union: The Potential for Multi-Level Control' (2002) 8 ELJ 59.

<sup>33</sup> This unfortunately does not facilitate non-geographically clustered minority viewpoints.

<sup>34</sup> J Hopkins, *Devolution in Context: Regional, Federal and Devolved Government in the European Union* (Cavendish, 2002), 3-16 and 34-6.

<sup>35</sup> Regarding local knowledge, generally: F Fischer, *Citizens, Experts, and the Environment* (Duke University Press, 2000), Part III; environmental: CM Raymond et al, 'Integrating local and scientific knowledge for environmental management' (2010) 91:8 Journal of Environmental Management 1766; and agricultural: M Carolan, 'Sustainable agriculture, science and the co-production of 'expert'

to have localised expertise and insight, which is not necessarily available to, or at least not an integral part of the general knowledge of, individuals from other areas who are representing the overall nation. Consequently, just as with the *implementation* or *enforcement* of policies, subnational bodies may be the appropriate place to *develop* some policies. Overall, they can provide a more localised approach based on relevant knowledge specific to the area and which reflects the values of the populace.

However, decentralisation is not a panacea, suffers limitations and may not even be desired by those on the ground. Instead, the nature of the issue or the context may call for decision-making at the transnational or global levels, e.g. regarding climate change and trade. Higher levels tend to have greater access to resources (e.g. scientific expertise and financial), reduce the likelihood of externalities (by internalising them in effect) and, through a hierarchical approach, may reduce conflicting and inefficient approaches.

Thus, neither a centralised nor a decentralised approach is perfect for every occasion, but either may be more appropriate in different contexts.<sup>36</sup> Subsidiarity takes advantage of this, by starting with a decentralised approach and moving to the centralised approach where more desirable – or, from the EU's perspective, where necessary and adding value.<sup>37</sup>

Therefore, subsidiarity-based multilevel governance 'may determine the most proper level for the exercise of power in terms of relative efficiency and democratic legitimacy.'<sup>38</sup> It casts aside the 'privileged position' of the nation-state, providing a framework for determining the allocation of power,<sup>39</sup> with a potential strong foundation in both input and output democracy,<sup>40</sup> if applied appropriately.<sup>41</sup> It also simply provides an alternative viewpoint for considering a contentious area, where the traditional approach has been 'all-or-nothing' and conflict dominates.

## 2.2 Challenges for operationalizing Subsidiarity-based Multilevel governance

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knowledge: the value of interactional expertise' (2006) 11:4 Local Environment: the International Journal of Justice and Sustainability 1354.

<sup>36</sup> C Coglianese and K Nicolaidis, 'Securing Subsidiarity: the institutional design of federalism in the United States and Europe' in Nicolaidis and Howse (n18), 278-9.

<sup>37</sup> Commission, 'Impact Assessment Guidelines', SEC(2009) 92, 21.

<sup>38</sup> W Vandenbruwaene, 'The legal enforcement of the principle of subsidiarity' E-(2014) 6:2 Perspectives on Federalism 45, [http://www.on-federalism.eu/attachments/004\\_Volume%206%20-%20Issue%202%20-%202014.pdf#page=58](http://www.on-federalism.eu/attachments/004_Volume%206%20-%20Issue%202%20-%202014.pdf#page=58), E-48. Similarly Hooghe and Marks (n16), 235-6.

<sup>39</sup> Hopkins (n34), 28-9.

<sup>40</sup> E.g. F Scharpf, *Governing in Europe: Effective and Democratic?*, (OUP, 1999), Introduction and Chapter 1; and VA Schmidt, 'Democracy and Legitimacy in the European Union Revisited: input, output and 'throughput'' (2013) 61 Political Studies 2. Traditionally democracy theory focuses more on input (government by the people), whilst output democracy considers also 'the common interests of the constituency' (Scharpf at 11) (government for the people).

<sup>41</sup> C Scott, 'Governing without law or governing without government? New-ish governance the legitimacy of the EU' (2009) 15 ELJ 160; and Vandenbruwaene (n38), E-51-2.

However, subsidiarity-based multilevel governance, which calls for powers to be located at the most appropriate level(s), leads to a very tangled web and raises numerous challenges and risks.<sup>42</sup>

### Identifying appropriate levels

The most fundamental challenge is identifying the ‘optimal’ or appropriate<sup>43</sup> level(s) for the allocation of powers (and indeed controls). This initially involves locating the core policy-making powers at the appropriate level(s), rather than automatically assigning them to the EU or national level. It also involves identifying the appropriate level(s) for any complementary/residual policy-making powers.<sup>44</sup> Core powers would encompass, for instance, the ability to set highly-detailed general standards, levels of protection and stances on an issue that will apply within the relevant territory, unless exceptions or limitations are applicable. Complementary/residual powers may involve for instance limited and controlled possibilities to increase/reduce levels of protection, derogate from the central approach or develop standards. The boundary between core and residual/complementary powers may not always be clear or precise, with a sliding scale where powers shift from one level to another. Further, this identification of the *loci* will rarely be entirely straightforward and the manner of its achievement will vary widely.<sup>45</sup> This is not helped by subsidiarity’s interdisciplinary nature, encompassing legal, political and economic aspects.<sup>46</sup> Nonetheless, (overlapping) criteria are identifiable<sup>47</sup> that reflect the two components of subsidiarity: input democracy and output democracy/efficiency.

First and foremost, one must identify the interests at stake, how important these issues are to the various levels,<sup>48</sup> what degree of homogeneity/consensus or heterogeneity/conflict exists in relation to the issues and to what extent the higher levels could accommodate the elements of heterogeneity. These elements primarily will indicate how important it is to allocate powers at the lower levels.

Second, one must consider elements relating to efficiency, including: where the expertise and relevant resources lie; what impacts the decisions will have beyond the initial jurisdiction or territory and whether these can be internalised; and how elements of heterogeneity would impact upon centralised actions. From an economic perspective, this therefore includes consideration of externalities and economies of

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<sup>42</sup> See C Charbit, ‘Governance of Public Policies in Decentralised Contexts – The Multi-level Approach’ *OECD Regional Development Working Papers*, 2011/04, OECD Publishing, <http://dx.doi.org/10.1787/5kg883pkxkxhc-en>, 14-6; and Estella (n19), 98-9 and 112-4 in particular.

<sup>43</sup> Coglianese and Nicolaidis (n36), 277-8.

<sup>44</sup> Similarly for ‘supporting’ (encompassing implementation and enforcement) powers.

<sup>45</sup> Charbit (n42), 13-5.

<sup>46</sup> E.g. G de Búrca, ‘Reappraising Subsidiarity’s Significance after Amsterdam’ (2000) Harvard Jean Monnet Working Paper 7/99, <https://infoeuropa.eu/rocid.pt/files/database/000036001-000037000/000036601.pdf>; and Commission, ‘Better Regulation Guidelines’ COM(2015)211, 21.

<sup>47</sup> E.g. de Búrca (n46), 31-2; J van Zeben, *The Allocation of Regulatory Competence in the EU Emissions Trading Scheme* (CUP, 2014), 12 and 55-6; SI Karlsson, ‘Allocating responsibilities in multi-level governance for sustainable development’ (2007) 34 *International Journal of Social Economics* 103; and J Pelkman, *European Integration: Methods and Economic Analysis*, (3<sup>rd</sup> edn, Pearson, 2006), 40-1 (N.B. this test is expressly limited as a functionality test in the EU context).

<sup>48</sup> Comparable to the ‘concern principle’ in Karlsson (n47), 108-9.



scale.<sup>49</sup> Some of these elements also reflect the ‘gaps’ that the OECD considers challenge effective and coherent multilevel governance,<sup>50</sup> e.g. those relating to capacity,<sup>51</sup> funding and administrative boundaries. If the gaps at the lower level are so significant or substantial that another level would be much more efficient, then it may indicate that the allocation of some or all powers to another level may be appropriate in the circumstances.<sup>52</sup> However, elsewhere it may be that the gaps may be resolved and instead relate more to the effective operationalisation of multilevel governance once the powers have been assigned.<sup>53</sup>

Finally it is necessary to evaluate whether the combined considerations favour centralising or decentralising powers. This involves an intricate balancing act, for which there is no clear-cut tipping point.<sup>54</sup> However, due to subsidiarity’s preference for lower level action, there needs to be a clear advantage in not merely the possibility of centralising policy-making powers, but in the nature and degree of centralisation also. If the issues are fundamental to the local level, with significant degrees of heterogeneity across the broader territory, then input democracy weighs heavily in favour of allocating the powers at the lower levels. This then increases the burden to establish the need for greater centralisation. If there is little heterogeneity, but considerable chance of externalities, then centralisation becomes more justifiable. However, even where efficiency calls for centralisation of powers, this does not mean centralising all powers or even the core powers – it is only to the extent required by considerations of efficiency, which impacts upon the detail, nature and permanency of any allocation and exercise of powers.

Significantly, if a relocation of authority is required, this will involve convincing the levels currently holding or controlling the division of power that such relocation is preferable. Furthermore, wherever the powers are initially allocated, it is necessary that controls exist that prevent a body misusing or even abusing their powers, e.g. through judicial challenges of actions as *ultra vires* or making the allocation of powers conditional.<sup>55</sup>

### **Maintaining coherence**

Once the powers have been allocated, there remains the challenge of maintaining an appropriate degree of cohesion or coherence.<sup>56</sup> This is because powers may now be dispersed vertically or horizontally, with overlapping competences at the different levels – whether related to single or multiple issues, within or across regimes. The complexity increases where multiple focuses for powers exist in a specific area, e.g.

<sup>49</sup> E.g. M Gilroy, V Seiler and H Schreckenber, ‘Subsidiarity between economic freedom and harmonized regulation: Is there an Optimal Degree of European Integration?’ (2013) 10:2 Federal Governance 3; Article 5(3) TEU; and Commission, ‘Impact Assessment Guidelines’, (n37), 22.

<sup>50</sup> Charbit (n42), 15-6.

<sup>51</sup> Karlsson (n47), 108.

<sup>52</sup> R Stoa, ‘Decentralization of Water Resources Management’ (2014) 10:2 Utrecht Law Review 31.

<sup>53</sup> E.g. Charbit (n42), 16-21.

<sup>54</sup> This also increases enforcement challenges regarding subsidiarity within the EU, e.g. S Constantin, ‘Rethinking Subsidiarity and the Balance of Powers in the EU in Light of the Lisbon Treaty and Beyond’ (2008) 4 CYELP 151; and Estella (n19), at 137-174 regarding the Court’s display of ‘prudence’.

<sup>55</sup> Coglianese and Nicolaidis (n36).

<sup>56</sup> OECD, *Water Governance in OECD Countries: A Multi-level Approach*, (2011) OECD Studies on Water, OECD Publishing, 19; and COM(2001)428, 7-8.

regarding trade, employment, health and the environment.<sup>57</sup> At the very least, the ‘functional interconnection between regulatory areas, and within the same regulatory area among different regulatory levels, makes the task of establishing clear dividing lines difficult.’<sup>58</sup> This may potentially lead to inefficient use of resources and conflicts between and across the different levels, including internal and external to the nation-state.<sup>59</sup> Consequently, it is also necessary to ensure coordination<sup>60</sup> and the development of harmonising structures/principles<sup>61</sup> to varying degrees.

In hierarchical situations with substantial harmonisation, coordination will typically automatically occur in line with the higher levels’ policy decisions. Yet, some minimal coordination remains essential where policy-making powers in an area are held over multiple levels (vertical coordination) or at several *loci* on the same level (horizontal coordination). This can be achieved via traditional government tools or wider governance approaches also, e.g. an overarching framework with minimum core standards and principles or through networks facilitating communication.

### **Conclusions on operationalizing subsidiarity-based multilevel governance**

Thus, subsidiarity-based multilevel governance does not necessitate that the requisite powers be present solely at one level or with one institution. It instead asks where the appropriate levels are for the core and complementary powers and then how to ensure coherency. It starts with some degree of preference for allocating the powers at the lower levels, which can be countered to varying degrees depending on factors impacting upon output democracy/efficiency. However, it is by no means a precise formula and the intricacies and overlapping issues within an area can make identifying the relevant *loci* and subsequently maintaining coherence a formidable task. Although challenging, subsidiarity-based multilevel governance is feasible<sup>62</sup> and a worthwhile endeavour to investigate. The following section undertakes an initial identification of potential appropriate *loci* for relevant powers.

## **3. MULTILEVEL GOVERNANCE FOR GM CULTIVATION?**

In considering the potential application of subsidiarity-based multilevel governance to the EU GM regime, one must first consider briefly the nature of GM cultivation as a form of agriculture that involves adaptation of DNA.

### ***Nature of GM cultivation***

Firstly, as a form of agriculture, GM cultivation plays a multifunctional role in society<sup>63</sup> and interacts with a wide-range of regimes and issues, including property rights, the market, society, farmer and consumer interests, environmental protection and health protection. These interactions are complex, occurring across sectors and levels. For instance, agricultural activities are impacted upon by local climatic, environmental and geographical conditions and affect a range of issues central to

<sup>57</sup> E.g. regarding water policy: OECD (n56).

<sup>58</sup> Estella (n19), 114.

<sup>59</sup> E.g. Chowdhury and Wessel (n15), 339; and Hooghe and Marks (n16), 239.

<sup>60</sup> Landy and Teles (n18), 414; and Vandenbruwaene, (n17), 231.

<sup>61</sup> COM(2001)428.

<sup>62</sup> E.g. Colombo (n20).

<sup>63</sup> Council Decision 2006/144/EC on Community strategic guidelines for rural development (programming period 2007 to 2013) [2006] OJ L 55/20, Recital 2 and Guidelines, Section 2.1.

local societies.<sup>64</sup> Consequently an entirely uniform approach to agriculture is not practically possible,<sup>65</sup> as evidenced by the Lisbon Treaty listing agriculture as an area of shared competence (Article 4 TFEU) and the current Common Agricultural Policy (CAP) reform providing greater freedom for Member States and potentially for regions.

However, agriculture is also directly relevant to the national, European and global levels, exemplified regarding trade and environmental protection. Consequently, CAP remains with some significant harmonisation at the EU level, e.g. regarding product standards, production practices, labelling, monitoring and traceability. Similarly, WTO instruments such as GATT, the SPS and TBT Agreements, and the Agreement on Agriculture are all applicable.

Furthermore, due to the environment's permeable nature and plants' propagation capacity, cultivation decisions at one location/level impact upon cultivation decisions elsewhere, irrespective of level and objectives. This is highlighted by the substantial difficulty currently in cultivating GM crops alongside non-GM crops without admixture (presence of GMOs in non-GM crops) occurring and one agri-type dominating over another,<sup>66</sup> i.e. harmonious coexistence. Therefore, the degree of practical choice (even where a legal one exists) for a legislative body or a producer may be significantly restricted by choices made elsewhere.<sup>67</sup>

Secondly, as GM cultivation results from adapting DNA, including across species, this entails both increased scientific uncertainty and moral concerns. Traditionally, science provides legitimacy in risk management, as subsequent decisions are founded upon objective 'truth' and thereby scientific rationality.<sup>68</sup> However, whilst fundamentally important in assessing the risks and benefits, science cannot provide definitive answers for instance regarding the rate of outcrossing (spread of GM material into other organisms) or how non-target organisms will be affected. Consequently, the same scientific evidence is capable of alternative interpretations and occasionally dissenting minority opinions regarding GMOs are visible even within the European Food Safety Authority (EFSA).<sup>69</sup> Linked to this, moral questions arise over, for instance, interfering with nature, the potential benefits and risks, double standards (e.g. if willing to import GM products but not to cultivate GM crops) and responsibilities owed to the world at large (e.g. if not willing to cultivate GM crops that might assist countries suffering from drought or malnutrition).

Together, these characteristics demonstrate the complexity in attempting to determine where authority should be allocated and help explain the continued conflict over GM

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<sup>64</sup> E.g. L. Bodiguel, 'Le territoire, vecteur de la reconnaissance juridique de l'agriculture multifonctionnelle' (2003) 273-4 *Économie rurale* 61.

<sup>65</sup> Different regional approaches exist even within a Member State: Case C-428/07 *Horvarth* [2009] ECR I-06355; and J Hunt, 'Devolution and differentiation: regional variation in EU law' (2010) 30:3 LS 421.

<sup>66</sup> M Dobbs, 'Excluding coexistence of GMOs? The impact of the EU Commission's 2010 Recommendation on coexistence' (2011) 20 *RECIEL* 180.

<sup>67</sup> M Dobbs, 'Co-existence of GMOs in the EU – A Veritable Choice for Whom?' in MN Cardwell and J McMahon (eds), *Research Handbook on EU Agriculture Law* (Edward Elgar, 2015).

<sup>68</sup> J Peel, *Science and Risk Regulation in International Law*, (CUP, 2010).

<sup>69</sup> E.g. Appendix D of 'Scientific Opinion of the Panel on Genetically Modified Organisms (GMO) and the Panel on Biological Hazards (BIOHAZ) on a request from the Commission on the use of antibiotic resistance genes as marker genes in genetically modified plants' [2009] 7(3) *The EFSA Journal*, 1034 1-81.

governance. They also impact upon the different issues in varying manners. Thus, whilst commonalities exist, depending on the issue considered there are considerable variations regarding for instance the degree of heterogeneity present, the relative capacity of the levels, the need to avoid a ‘race to the bottom’ and the nature of the relevant externalities. Consequently, it is useful to differentiate between the various aspects central to GM cultivation and consider whether these should be regulated at different levels.<sup>70</sup> In particular, a key division can be made between environmental and health protection on the one hand and other facets on the other hand (with trade considered as an overlapping feature/externality).

### *Issues at stake*

Regarding environmental and health protection, a range of factors impact especially upon the question of efficiency/output democracy. Here, firstly the capacity varies across the levels. As noted, lower levels hold greater knowledge and expertise regarding relevant local environmental, geographical and conditions as well as practices. However, higher levels tend to have access to broader scientific knowledge and expertise regarding GM technology and general impacts. Centralisation also enables multiple sources and viewpoints to be gathered before developing a final scientific opinion. Secondly, a general desire exists to avoid a potential race to the bottom – for instance, high levels of environmental and health protection are generally promoted in the EU context as reflected in the Treaties. However, complete decentralisation might encourage lax regulation to facilitate the increased use of GM crops and trade, thereby garnering economic benefits relative to other States or regions (prisoner’s dilemma). Thirdly, and related to the previous point, in light of the permeability of nature there is the real possibility of extraterritorial environmental and health impacts. Fourthly, more generally any measures will impact upon the trade of seeds and eventual products, indicating that further externalities need to be borne in mind – especially in the context of the EU’s internal market.

It is arguable that these factors outweigh subsidiarity’s preference in favour of lower levels, due to a combination of externalities and the EU’s superior resources, and that therefore powers regarding environmental and health protection should usually be centralized.<sup>71</sup> This would encompass initial and subsequent assessments, the (re)authorisation (or revocation) decision and accompanying conditions, as well as more generally the setting of safety standards and best practices. Thus, the main role for lower levels would be funnelling information to the higher levels and implementing the resulting science-based decisions.

However, the factors do not necessitate complete centralisation and two significant limitations arguably should apply, due primarily to scientific uncertainty in conjunction with the precautionary principle and the impact of local environmental, geographical and climatic conditions. Whilst externalities are still relevant, the capacity of the higher levels is not so obviously dominant. Further, the issues remain relevant to the lower levels and there are also considerations over risk diversification

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<sup>70</sup> Similarly regarding climate change and water: J Scott and M Maslin, ‘Carbon Trading Needs a Multi-Level Approach’ (2011) 7357 Nature 445; and OECD (n56), at 19.

<sup>71</sup> Cf. T Bernauer and L Caduff, ‘European Food Safety: Multilevel Governance, Re-Nationalization or Centralization?’ (2004) Working Paper No.3, Centre for Comparative and International Studies, ETH Zurich and University of Zurich, available at <http://ssrn.com/abstract=1514454>.

in case the central level makes ‘the wrong decision’.<sup>72</sup> Firstly, this would call for flexibility regarding the assessment of evidence, whereby assessors at any level could consider new evidence<sup>73</sup>/different interpretations of existing evidence resulting in a conflicting opinion.<sup>74</sup> Secondly, it would call for flexibility regarding risk management, whereby other considerations such as morality or freedom of choice might grow in significance regarding decision-making and also national, regional or local decision-makers might aim for higher levels of environmental or health protection. Together these reflect a modified concept of scientific rationality, whereby science remains highly regarded but is not the source of absolute truth, leading to a more solid foundation in legitimacy.<sup>75</sup> Clearly, to avoid being abused to justify any subjective and potentially irrational/discriminatory/protectionist measures, it would need effective controls. Thus, the central level (here the EU) should still determine if the alternative conclusions from the risk assessment were reasonable<sup>76</sup> and whether the resulting measures were proportionate.

However, the factors impact differently regarding land-use aspects other than environmental and health risks, such as agricultural policies, consumer choice and public morals. Here, in light of the relative significance of local knowledge and experience,<sup>77</sup> the local levels are unlikely to suffer severe capacity gaps. There are also no further externalities (there is some limited impact upon cultivation in neighbouring territories and upon trade more generally). These factors together suggest that most of the powers should remain at the lower levels, with some limited controls at the higher levels to help manage the externalities. This would facilitate local considerations and conditions to be taken more effectively into account and reflect the society in question’s values.<sup>78</sup> Nonetheless, whilst ideally such policy decisions should be made as low as feasible, pragmatically there must be a cut-off point. Logically, subnational *legislative* regions with relevant powers within their Member State should maintain these powers, as they have long established their desire and intent to act in this area in a manner that is potentially at odds with the national approach, even if finally they decide to mirror the overall national approach! Although seemingly a *fait accompli*, significant challenges exist in ensuring that these regions can actually avail of their powers, as seen below. If other subnational regions or lower levels are able to demonstrate sufficient cause (and capacity), then it may be appropriate that they also hold relevant policy-making powers.

However, as with scientific elements, the issue is not that simple. In particular, the supposed heterogeneity regarding these broader policies and issues may not exist within various territories. In that case, the lower levels may not take the initiative to act. Consequently, these powers should be located with what appears to be the appropriate level initially (subnational or national), but with a fall-back towards the

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<sup>72</sup> E.g. van Zeben (n47), 30.

<sup>73</sup> Including regarding relevant local conditions.

<sup>74</sup> E.g. M Dobbs, ‘Legalising general prohibitions on cultivation of genetically modified organisms’ (2010) 11 GLJ 1347, at Section B.I regarding the role of safeguard clauses.

<sup>75</sup> L Levidow, ‘Precautionary Uncertainty: Regulating GM Crops in Europe’ (2001) 31 Social Studies of Science 848.

<sup>76</sup> If not to be arbitrary, then the measures must be objectively based and the risk assessment should still play an important role. Any conclusions drawn from the assessment must logically flow. This approach is paralleled in: Commission’s Communication on the precautionary principle COM/2000/0001 final, p.9.

<sup>77</sup> See n35.

<sup>78</sup> Lee (n12), 122.



central level (national and EU) where not availed of – or alternatively, the central powers can act first with broad derogations then available for the lower levels. Furthermore, there is interaction and overlap with various disciplines and issues where the appropriate level(s) may be at the higher levels, e.g. protection of the internal market. This overlap calls for some central controls again over national and regional powers to avoid abuse or misuse.

The complexity and dispersal of powers over the levels heightens both the challenge and need for coherency, without which both the decentralised and centralised approaches could risk being substantially undermined. Some vertical and horizontal coordination will be required due to the ordinary challenges for multilevel governance and ensuring efficiency, e.g. avoiding duplication or contradiction of measures where powers are shared between the different levels. However, coordination is also necessary to further the protection of heterogeneous approaches; local cultivation policies cannot exist entirely independently, due especially to the challenges of coexistence. Thus, in apparent contradiction, this may involve some degree of harmonisation/centralisation. However, this may be achieved in an informal manner rather than through government.

Overall, the initial exploration indicates that GM cultivation calls for varying approaches to its governance, depending on the issue at hand. Whilst the core policy-making powers regarding environmental and health aspects should be situated predominately at the higher levels and therefore with the EU in this context, other elements should be predominately situated at lower levels, encompassing therein the national and subnational levels as appropriate. However, it is also essential that relevant complementary powers be held across the levels<sup>79</sup> and structures be put in place to ensure coherency and effectiveness. Whilst the suggested allocation of powers is not definitive and further investigation is needed, it provides a starting point for analysing the distribution of powers within the EU. The following section examines the nature of the post-authorisation powers left to Member States and regions in light of these observations<sup>80</sup> and considers whether changes are desirable and feasible.

#### **4. MULTILEVEL GOVERNANCE IN THE EU GM CULTIVATION REGIME?**

Fundamentally, the overall EU GM cultivation regime is highly harmonised. This is reflected in the legal base of the core legislation (Deliberate Release Directive 2001/18<sup>81</sup> and Regulations 1829/2003 on GM food and feed<sup>82</sup> and 1830/2003 on the labelling and traceability of GMOs)<sup>83</sup> being Article 114 TFEU regarding the harmonisation of the internal market, rather than for instance Article 191 TFEU on the environment. This harmonisation places the predominate powers regarding authorisation, encompassing scientific elements and broader policy choices, at the EU level rather than at national or regional levels. Following EU authorisation, Member States and their regions may not hinder the free movement of the authorised seeds

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<sup>79</sup> This reflects the challenges in identifying a single optimal level: Lee (n11).

<sup>80</sup> The framework could be applied to authorisations similarly.

<sup>81</sup> [2001] OJ L106/1.

<sup>82</sup> [2003] OJ L 268/1.

<sup>83</sup> [2003] OJ L268/24.

(including for cultivation) or eventual products, except in accordance with EU law.<sup>84</sup> Consequently, the starting point for considering the post-authorisation powers of the Member States and subnational regions is that they operate within a highly centralised regime with a high degree of coherency in principle.

However, EU law provides for a number of mechanisms whereby Member States, and potentially their subnational regions, may subsequently act unilaterally. The main existing mechanisms are safeguard clauses, an opt-out clause and a coexistence clause.

#### **4.1 Threats to the environment or human health: safeguard clauses**

Safeguard clauses, broadly understood, provide for the EU or Member States (but not expressly regions) to act swiftly post-authorisation where specific conditions are fulfilled. They focus heavily on environmental or human health protection, whereas these are mainly excluded from the other mechanisms. The core clauses enabling Member State action regarding GM cultivation are Article 23 of Directive 2001/18, Article 34 of Regulation 1829/2003 and Article 114(5) TFEU. However, a combination of their content (and interpretation thereof) and the applicable procedures/roles of the parties limits the clauses' role and promotes a high degree of centralisation.<sup>85</sup>

Initially, the Member States (or potentially regions) choose the measures based on their own assessments. However, the EU level determines whether the criteria are met and whether the measures are appropriate. Specifically, the Commission evaluates the measures (followed by the comitology procedure for Articles 23 and 34), typically relying heavily upon EFSA's Opinions regarding the risks,<sup>86</sup> with potential for review by the EU Courts. In principle therefore, the process is a highly centralised mechanism. In practice, it has not operated in such a manner in this context. To date, the Commission has not been able to lift national cultivation bans, despite considering them illegal,<sup>87</sup> due to the blocking role of the Council in the comitology procedure.<sup>88</sup> However, the amended comitology procedure replaces the Council with an appeal committee and, whilst the appeal committee comprises of national representatives, there is no guarantee that it will replicate the Council's or national executives' views and approaches. Further, the measures can also be challenged by parties with standing

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<sup>84</sup> M Lee, *EU Environmental Law, Governance and Decision-Making*, 2<sup>nd</sup> ed. (Hart, 2014), 237-8 and 246; and N de Sadeleer, *EU Environmental Law and the Internal Market* (OUP, 2014), 249-300 and 349-382.

<sup>85</sup> Lee (n84), 225-234; FM Fleurke, 'What use for Article 95(5) EC?' (2008) 20(2) JEL 267; and Weimer (n12).

<sup>86</sup> See J Scott and E Vos, 'The Juridification of Uncertainty; Observations on the Ambivalence of the Precautionary Principle within the EU and the WTO' in C Joerges and R Dehousse (eds), *Good Governance in Europe's Integrated Market* (OUP, 2002).

<sup>87</sup> See COM(2005)161-169, 'Proposals to Compel Member States to Remove Safeguard Measures as Unjustified'.

<sup>88</sup> E.g. Commission Decision 2008/495/EC concerning the provisional prohibition of the use and sale in Austria of genetically modified maize (*Zea mays* L. line MON810) pursuant to Directive 2001/18/EC of the European Parliament and of the Council, [2008] OJ L172/25.

irrespective of the outcome of the comitology process, as occurred in *Monsanto France* recently.<sup>89</sup>

The content and interpretation of the provisions further restrict their potential role, as exemplified by the requirement of ‘newness’. Article 23 and Article 114(5) TFEU require ‘new’ information or scientific evidence, and the Court of Justice (ECJ) recently interpreted Article 34 to this end also.<sup>90</sup> The Courts have interpreted this criterion restrictively regarding Article 114(5) TFEU<sup>91</sup> and Article 34,<sup>92</sup> with a similarly restrictive approach likely for Article 23. This currently excludes for instance new (reasonable) interpretations of existing scientific evidence, despite support for this by AG Sharpston<sup>93</sup> and the possibility to interpret Article 23 in particular more flexibly.<sup>94</sup> This restrictive approach is reflected in the fact that the Commission and EFSA have yet to consider any such safeguard measures as justified, primarily due to a lack of relevant new or additional scientific information.<sup>95</sup>

Furthermore, the ECJ recently imposed further serious restrictions in *Monsanto France* where it indicated that Article 34 (rather than Article 23) applied, where a GM crop was also authorised for food or feed.<sup>96</sup> This reflects a further push by the EU towards centralisation, with significant impacts upon the process, the content and interpretation of the content.<sup>97</sup> Firstly, Article 34 involves a ‘residual right’ that permits ‘emergency measures’ by the Member States only where the Commission does not act to take protective measures,<sup>98</sup> whereas Article 23 leaves the initial right to derogate with the Member States.<sup>99</sup> Secondly, Article 34 contains stricter criteria and, although capable of a flexible interpretation,<sup>100</sup> the ECJ made no reference to scientific uncertainty or the precautionary principle, in contrast with its earlier case-law.<sup>101</sup> This makes it increasingly difficult for Member States to rely upon divergent risk assessments and increases the standard of proof regarding risk.

<sup>89</sup> E.g. Joined Cases C-58/10 to C-68/10 *Monsanto SAS and Others v Ministre de l’Agriculture et de la Pêche*, [2011] ECR I-7763.

<sup>90</sup> *Monsanto (France)* (n89), [76-8] in particular.

<sup>91</sup> E.g. Joined Cases T-366/03 and T-235/04 *Land Oberösterreich and Republic of Austria v Commission* [2005] ECR II-4005.

<sup>92</sup> *Monsanto (France)* (n89), [76-8]; and Weimer (n12).

<sup>93</sup> See Opinion of 15 May 2007 of AG Sharpston in Joined Cases C-439/05 and C-454/05 *Land Oberösterreich and Austria v Commission* [2007] ECR I-07141, [142].

<sup>94</sup> As noted by T Hervey, ‘Regulation of Genetically Modified Products in a Multi-Level System of Governance: Science or Citizens?’ (2001) 10:3 RECIEL 321, fn72, Article 23 refers to ‘reassessments’. However, the phrasing in English indicates that reassessments should be affected due to new or additional information. Arguably, other versions (e.g. German) provide further support for a more flexible interpretation (different placing of commas and terminology). However, Case C-121/07 *Commission v France* [2008] ECR I-9519 indicated that including reassessments/re-interpretations breached Directive 2001/18.

<sup>95</sup> COM(2005)161–169. Other criteria apply to each clause and are also applied strictly – See n85.

<sup>96</sup> Weimer (n12), 451; and Lee (n84), 232-4.

<sup>97</sup> M Lee, *EU regulation of GMOs: Law and Decision Making for a New Technology*, (Edward Elgar, 2008), 92.

<sup>98</sup> Weimer (n12), 450.

<sup>99</sup> Lee (n84), 234.

<sup>100</sup> See Opinion of 22 March 2011 of AG Mengozzi in *Monsanto (France)* (n89).

<sup>101</sup> Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105, [112].

Regarding the risk management aspect,<sup>102</sup> the level of protection sought fundamentally affects any determination of whether the measures are proportionate. Due to the legal base in Article 114 TFEU and the degree of harmonisation (maximum), neither at the authorisation stage nor in availing of safeguard clauses may Member States unilaterally aim for a higher level of protection – the level of protection is that already chosen by the EU.

Finally, as hinted at, the clauses do not guarantee subnational regions any role, but only refer to the States. Austria has demonstrated that subnational regions can attempt to rely upon the safeguard clauses even before the ECJ,<sup>103</sup> but this role is dependent upon the support of their Member States.

Consequently, the safeguard clauses are important regarding environmental and health protection, but whilst there is some multilevel governance it is not truly subsidiarity-based. As the ECJ stated recently, in light of Regulation 1829/2003's objective 'of avoiding artificial disparities in the treatment of a serious risk, the assessment and management of a serious and evident risk ultimately come under the sole responsibility of the Commission and the Council, subject to review by the European Union Courts.'<sup>104</sup> The Member States and subnational regions' potential to avail of the safeguard clauses is greatly restricted by the criteria and their restrictive interpretation at the EU level, leading to a high level of centralisation of the core policy-making powers and no effective decentralisation of complementary powers. If there were broad scientific certainty and all concerned wished for the same level of environmental and health protection, this might suffice. Indeed, it is appropriate that the EU retain the core powers regarding risk assessment especially. However, the role left to Member States and especially regions is excessively limited in light of the abovementioned characteristics of GM cultivation, including the on-going scientific uncertainty.

### **Incorporating flexibility to facilitate subsidiarity-based multilevel governance?**

In light of the proposed appropriate division (Section 3), the current approach could be ameliorated by a number of key changes – either by adapting the text or interpretation of the safeguard clauses or providing new complementary mechanisms also focussed on environmental and health protection, whilst still retaining controls at the EU level.

Firstly, regarding the risk assessments, the inclusion of different interpretations or even re-interpretations of existing information would reflect the continuing scientific uncertainty as noted above. Whilst technically possible through a more generous interpretation of existing provisions, this would most likely require legislative revision. Article 12 of the 1997 Novel Foods Regulation, which exemplifies this option, provides for Member State actions where their concerns are due to 'new information or a reassessment of existing information'.<sup>105</sup> Secondly, changes could be

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<sup>102</sup> Although customary in considering risk analysis, separating risk assessment and management is somewhat artificial. In practice, the components overlap and the process is necessarily circular and iterative if to be effective: e.g. YY Haimes, *Risk Modeling, Assessment and Management*, (2<sup>nd</sup> edn, Wiley, 2005), 21-22 and 54-8.

<sup>103</sup> E.g. Joined Cases C-439/05 and C-454/05 *Land Oberösterreich* (n93).

<sup>104</sup> *Monsanto (France)* (n89), [78].

<sup>105</sup> Regulation 258/97, [1997] OJ L43/1.

made to facilitate Member States in upholding a higher standard of protection, e.g. through incorporating such a possibility directly into Articles 23 or 34, or changing the predominate legal basis of the GM legislation to Article 192 TFEU.<sup>106</sup> This would thereby impact upon any determination of the proportionality of resulting protective measures. Thirdly, as is discussed in Section 4.3 below, the clauses could be adapted to facilitate the subnational bodies in acting in the same manner as the Member States, at least to the extent permitted by their national constitutional frameworks. The obvious alternative to adjusting the (approach to) safeguard clauses would be to amend the opt-out clause to include environmental and health concerns, including where already dealt with at the EU level, but with some control by the EU level once more.

These changes would facilitate lower levels acting where there are real concerns regarding the environment or human health, without surreptitiously availing of other mechanisms, and whilst still retaining overall EU control and ensuring coordination. However, they would also significantly alter the current approach, lead to some de-harmonisation and likely prove problematic and contentious – with external and internal pressures making such changes unlikely.<sup>107</sup> This is highlighted by the 2010 Cultivation Package and Directive 2015/412, which repeatedly confirm that environmental and health aspects are to remain harmonised,<sup>108</sup> despite the de-harmonisation of other aspects.

The most significant external pressure relates to the SPS Agreement, which is pivotal to discussions on GM cultivation.<sup>109</sup> The SPS Agreement, as interpreted by the WTO's Dispute Panel and the Appellate Board,<sup>110</sup> requires that State SPS measures generally be based on an appropriate risk assessment.<sup>111</sup> Although challenging, the Agreement does not pose any insurmountable obstacles to the proposed changes. Firstly, States may determine their own level of protection.<sup>112</sup> Secondly, the possibility of valid minority views and diverging opinions found within a risk assessment is recognised by the WTO,<sup>113</sup> such that a 'single risk assessment might conceivably provide a basis for different types of SPS measures'.<sup>114</sup> Thirdly, where there is insufficient scientific evidence in light of the level chosen,<sup>115</sup> States may take provisional measures based on available pertinent information, whilst they seek

<sup>106</sup> Member States could thereby aim for a higher level of environmental protection under Article 193 TFEU. They would also not require new information, but would still need to comply with EU internal market law: de Sadeleer (n84), 350-7. This would denote a clear change from maximum to minimum harmonization.

<sup>107</sup> Randour, Janssens and Delreux, (n6).

<sup>108</sup> E.g. COM(2010)380; COM(2010)375; and Directive 2015/412, Recitals 6 and 14.

<sup>109</sup> Lee (n97), 211.

<sup>110</sup> See J Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures – A Commentary* (OUP, 2009) and especially v-x and 76-138 regarding the scientific aspects. In the context of the EU regime, see Lee (n97), 211-222.

<sup>111</sup> 'European Communities – Measures Affecting the Approval and Marketing of Biotech Products', WT/DS291/R, WT/DS292/R and WT/DS293/R, DSR 2006:III, 847 (EC Biotech). For further see Annex A, pt.4 of the SPS Agreement; *Hormones*, para 200; and Lee (n97), 215.

<sup>112</sup> Article 3.3 and 4.1 of the SPS Agreement.

<sup>113</sup> *Hormones*, para 194.

<sup>114</sup> *EC Biotech*, pt. 7.3060.

<sup>115</sup> See United States – Continued Suspension of Obligations in the EC- Hormones Dispute WT/DS320/AB/R, paras 703 and 725 in particular (*Hormones II*); and Scott (n110), vii-ix.



additional information.<sup>116</sup> States also may rely upon new evidence that, whilst ‘falling short of a risk assessment’,<sup>117</sup> nonetheless casts doubt on whether the existing sufficient evidence ‘still permits a sufficiently objective assessment of risk’.<sup>118</sup> Thus, the flexible approach proposed could be facilitated by the SPS Agreement, provided that the States base their measures upon a suitable risk assessment or, where there is insufficient scientific evidence, other available pertinent information.

The vehement rejection of sharing powers regarding risk assessments and management is likely due to internal pressures. One such pressure is the desire to support the perception of EFSA as a source of objective expertise and of the rigorousness of the authorisation process and overall regime— a desire heightened by a range of food and health scandals, including ones regarding BSE/vCJD and more recently horsemeat.<sup>119</sup> This operates in conjunction with the related internal pressure of the internal market, which is generally promoted through maximum harmonisation. Hence, a desire for tightly controlled safeguard clauses. Even Article 12 of the Novel Foods Regulation appears likely to be repealed when the legislation is updated,<sup>120</sup> with the safeguard clause in the General Food Law<sup>121</sup> applying instead – one that does not specifically include measures based on reassessments of information and similarly to Article 34 of Regulation 1829/2003 leaves only a residual role to the Member States.<sup>122</sup>

Yet, the resulting fixation on maximum harmonisation of the risk components to the exclusion of any flexibility for Member States or regions is neither logical nor necessary. Firstly, such changes would involve limited de-harmonisation with negligible impact on the internal market compared to the recent opt-out clause. This is especially the case as the EU would still retain ultimate control and the EU level of protection is high. Even if it were considered to be technically minimum harmonisation, the tightly regulated regime would not give Member States a *carte blanche* and would still approximate maximum harmonisation.<sup>123</sup> Secondly, such an approach might be understandable where there is scientific certainty, but this is not the case here. Indeed, it reflects issues that arose regarding BSE/vCJD where the impact on trust was more severe due to the portrayal of scientifically established safety even though scientific uncertainty was abundant.<sup>124</sup> Implying that the products must be safe because of a positive Opinion by EFSA runs a similar risk. It also

<sup>116</sup> Article 5.7 of the SPS Agreement; and Scott (n110), vii-ix.

<sup>117</sup> Scott (n110), vii.

<sup>118</sup> *Hormones II*, para 725.

<sup>119</sup> E.g. L Levidow and S Carr, ‘Europeanising Advisory Expertise: The role ‘independent, objective and transparent’ scientific advice in agri-biotech regulation’ (2007) 25 Environment and Planning C: Government and Politics 880.

<sup>120</sup> Commission Proposal for a Regulation of the European Parliament and of the Council on novel foods, COM(2013)894, which would replace the 1997 Novel Foods Regulation, contains no such safeguard clause.

<sup>121</sup> Regulation 178/2002/EC, [2002] OJ L31/1.

<sup>122</sup> See Lee (n97), 92, regarding Article 34 of Regulation 1829/2003 and Article 54 of the General Food Law.

<sup>123</sup> C Twigg-Flesner, *The Europeanisation of Contract Law: Current Controversies in Law*, (Routledge, 2013) at 44.

<sup>124</sup> E Millstone and P van Zwanenberg, ‘A crisis of trust: for science, scientists or for institutions?’ (2000) Nature America 1307.

conflicts with Article 30 of the General Food Law, which expressly encourages dialogue between competent authorities and EFSA, with scope to include differing opinions within EFSA's Opinions. By indicating that some flexibility is available where there are real concerns, irrespective of the 'newness' of the supporting evidence, it actually helps foster trust in the overall system and thereby in authorised products. Further, the current practice of (unapproved) safeguard measures already challenges both the internal market and the perception of the authorisation process and regime's safety, rather than merely just the individual product.

Even so, unless other forces are brought to bear on the Commission and the EU as a whole, it is unlikely that these changes will occur. One potential source of pressure relates to the use of the new opt-out clause (Article 26b of Directive 2001/18). This provision can be seen as a last-ditch attempt to bolster the EU's control over the risk components of the controversial and battered GM cultivation regime. In principle, if Member States or regions continue to impose bans under the safeguard clauses and maintain that their bans truly are for environmental or human health concerns, rather than availing of Article 26b, some decentralisation of these aspects might occur. It is to Article 26b and its neighbour in the coexistence provision that we now turn.

#### **4.2 (Sub)National restrictions on cultivation: Article 26 of Directive 2001/18**

Articles 26a (since 2003) and 26b (since April 2015) provide the Member States with some significant powers to act unilaterally and restrict GM cultivation. Together, their fundamental purpose is to facilitate the Member States in choosing whether to engage in GM cultivation or not and, if so, to what degree – despite EU authorisation and without contesting the EU risk assessment or management decisions.

##### ***Article 26b – 'opt-out' clause***

Following Member States' requests,<sup>125</sup> a Commission Proposal<sup>126</sup> and subsequent lengthy and difficult negotiations at the EU level,<sup>127</sup> political agreement was reached on an opt-out clause. The result was Directive 2015/412, which inserted Article 26b (and the transitional Article 26c) into Directive 2001/18. Directive 2015/412 is based on Article 114 TFEU on harmonisation, whilst Recital 6 expressly refers to Article 2(2) TFEU, according to which Member States 'shall again exercise their competence to the extent that the Union has decided to cease exercising its competence.' Consequently, it aims to restore to Member States an element of power regarding post-authorisation cultivation.<sup>128</sup> Article 26b thereby provides for Member States to demand a geographical restriction from the notifier (*via* the Commission) during the (re-)authorisation process<sup>129</sup> and/or unilaterally impose such a geographical restriction at any time.

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<sup>125</sup> See (n1).

<sup>126</sup> COM(2010)375.

<sup>127</sup> M Weimer, 'Risk regulation, GMOs, and the challenges to deliberation in EU governance: politicization and scientification as co-producing trends' 2014-03 Amsterdam Centre for European Law and Governance Working Paper Series, at 33.

<sup>128</sup> Regarding the initial Proposal, see: COM(2010)380, Section 3; and Weimer (n127), 32-3.

<sup>129</sup> If the notifier does not refuse the demand, then the (re-)authorisation application will automatically be adjusted to reflect the restriction.

Crucially, Article 26b omits significant procedural limitations proposed by a Greek compromise<sup>130</sup> in 2014.<sup>131</sup> The Greek compromise required that any Member State wishing to restrict cultivation of a GM crop firstly must negotiate with a notifier *during* the (re-)authorisation process. This raises concerns of either substantial delays in authorisation, whilst Member States consult their populace/regions each and every time, or alternatively conclusion of the authorisation process without Member States having sufficient opportunity to consult or react.<sup>132</sup> Only if a notifier refused a restriction to a Member State might that *same* Member State then avail of the opt-out. Consequently, the compromise imposed significant restrictions and created a sense of urgency that would not readily facilitate consideration of regional viewpoints, changes of mind or developments in approaches.<sup>133</sup> The only flexibility in this regard would be if there were ‘new objective circumstances’, with no guarantee that this would be interpreted liberally. Although Recital 13 of Directive 2015/412 creates an expectation that most restrictions will be implemented at the (re-)authorisation stage, i.e. through making a demand of the notifier, the Member States may now opt-out at any stage whether they requested a geographical restriction previously or not.

However, Article 26b still imposes criteria on the Member States seeking to impose restrictions unilaterally. As with earlier proposed formulations, these restrictions must not impact upon authorised crops already planted and must be in compliance with EU law.<sup>134</sup> In particular, any measures must aim to fulfil a legitimate objective in a proportionate and non-discriminatory manner.<sup>135</sup> In this respect, Article 26b(3) includes a *non-exhaustive* list of objectives that encompasses agricultural policy, socioeconomic impacts and prevention of admixture. Importantly, as not harmonised, the Member States may determine the level of protection.

Further, unlike the 2010 Proposal,<sup>136</sup> Article 26b(3) includes ‘environmental policy objectives’ provided that they do not conflict with the environmental risk assessment carried out in accordance with the EU legislation. Although likely to be interpreted strictly, this supplements the overall environmental protection, for instance, in the case of local factors not considered during authorisation.

Overall, Article 26b returns significant powers to the Member States regarding policies/objectives most suited to be dealt with nationally or lower. Combined with Article 26a discussed below, Member States may make policy choices and take

<sup>130</sup> Annex to Council of the EU, *Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory – political agreement*, Brussels, 28 May 2014 (10271/14).

<sup>131</sup> Council of the EU, Press Release, 12 June 2014 (10415/14): [http://www.consilium.europa.eu/uedocs/cms\\_data/docs/pressdata/en/envir/143178.pdf](http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/envir/143178.pdf).

<sup>132</sup> EPEC, ‘Evaluation of the EU legislative framework in the field of cultivation of GMOs under Directive 2001/18/EC and Regulation (EC) 1829/2003, and the placing on the market of GMOs as or in products under Directive 2001/18/EC’, Final Report to DG SANCO, March 2011: [http://ec.europa.eu/food/food/biotechnology/evaluation/docs/gmo\\_cultivation\\_report\\_en.pdf](http://ec.europa.eu/food/food/biotechnology/evaluation/docs/gmo_cultivation_report_en.pdf), 96-7 and 106-7.

<sup>133</sup> EPEC, *ibid*, 106-7.

<sup>134</sup> S Poli ‘The Commission’s new approach to the cultivation of genetically modified organisms’ (2010) 1 EJRR 339, at 342-3; and Lee (n84), 246.

<sup>135</sup> COM(2010)375, Recital 8 of the Proposed Regulation and Section 3.1.2 of the Explanatory Memorandum; and Lee (n11), 374-8.

<sup>136</sup> COM(2010)375.

unilateral actions without needing to link them to the safeguard clauses.<sup>137</sup> Although Member States will need to tread carefully in identifying a relevant objective justification at both EU and WTO levels, it is feasible in principle.<sup>138</sup> Further, if notifiers agree to self-impose geographical limitations, this would arguably avoid WTO law, similarly to voluntary GM-free regions, as WTO law is aimed at States<sup>139</sup> and these are private, non-mandatory measures in appearance.<sup>140</sup> Consequently, the adopted text provides the Member States with significant flexibility, balanced by the obligation to justify restrictions where the notifier rejects their demands and not to affect authorised plants already planted.

However, despite the reference to decisions at the ‘national, regional or local level’ within the Explanatory Memorandum<sup>141</sup> and support by academics, the Committee of Regions and the European Parliament for such a role,<sup>142</sup> the regions remain without any independent powers. Even those subnational regions that have relevant legislative powers devolved to them under the national constitutional frameworks are reliant upon their Member States to support them in availing of Article 26b.<sup>143</sup>

With the exception of the subnational regions, considered in Section 4.3 below, there is clearly a shift of core powers downwards that reflects subsidiarity-based multilevel governance. However, this shift increases the importance of ensuring appropriate coordination within and between Member States, which is highlighted by consideration of coexistence.

#### **Article 26a – coexistence clause**

Despite the practical challenges noted above, the EU’s stance is that coexistence is possible and should be striven for, without excluding any agri-type in principle.<sup>144</sup> However, to achieve this, the EU acknowledges that some restrictions may be necessary to limit admixture. Article 26a thereby permits Member States to create ‘appropriate measures to avoid the unintended presence of GMOs in other products’ predominately in order to protect consumer and producer choice. From 2017, Article 26a as amended by Directive 2015/412, will also require Member States to create

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<sup>137</sup> Hervey (n94), 330 considered that the system’s focus on science and risks ‘obfuscate[d] competing interests’.

<sup>138</sup> Dobbs (n67), Section 6(b).

<sup>139</sup> Panel Report, Argentina - Measures affecting the export of bovine hides and the import of finished leather, Panel Report, WT/DS155/R, para. 11.18.

<sup>140</sup> However, if there is ‘sufficient governmental involvement’ then the measures could fall foul of GATT and would need to be justified, e.g. potentially if States negotiate with notifiers to obtain their agreement: Panel Report, Japan – Measures Affecting Consumer Photographic Film and Paper, WT/DS44/R, para. 10.56.

<sup>141</sup> COM(2010)375, 6.

<sup>142</sup> Hunt (n65); European Parliament, *Legislative Resolution of 5 July 2011 on the Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as Regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of GMOs in their Territory* (COM(2010)0375–C7-0178/2010–2010/0208(COD)), 8; and Committee of the Regions, Opinion on ‘Freedom for Member States to Decide on the Cultivation of Crops in their Territory’, [2011] OJ C104/13, [18].

<sup>143</sup> M Dobbs, ‘Choosing to go GM-Free?’, EU Law Analysis, 24<sup>th</sup> March 2015, <http://eulawanalysis.blogspot.co.uk/2015/03/choosing-to-go-gm-free-new-eu-legal.html>.

<sup>144</sup> 2003 Co-existence Recommendation, Guidelines, Section 1.1; COM(2006)104, Section 3; and Commission Staff Working document, SEC(2006)313, annexed to COM(2006)104, 6 and 8.

cross-border measures. In doing so, it provides Member States with further powers and also could facilitate, or destroy, coherency in the regime.

Despite the apparent de-harmonisation by Article 26a, the Commission subsequently took measures that softly harmonised the area in a quite restrictive manner.<sup>145</sup> This is exemplified by the creation of the 2003 Co-existence Recommendation<sup>146</sup> and the Network Group for the Exchange and Coordination of Information Concerning Coexistence of Genetically Modified, Conventional and Organic Crops (COEX-NET) that comprises of Member States but is chaired by the Commission. These two elements furthered a relatively homogenous approach reflecting the Commission's understanding of coexistence – focused on producer choice and specifically the *economic* impact on a producer's ability to cultivate their chosen agri-type (linked to labelling requirements).<sup>147</sup>

However, wide variations in coexistence measures continued, some Member States did not create any measures<sup>148</sup> and regions were declaring themselves as GM-free. The Commission eventually responded with its 2010 Coexistence Recommendation, replacing the 2003 Recommendation. This takes a somewhat more flexible approach and notes that producers may wish to aim for minimal or even zero admixture and Member States 'should consider the possibility' of creating exclusion zones or GM-free regions where proportionate.<sup>149</sup> Further, the ECJ has indicated that Article 26a may permit 'geographically restricted prohibitions'.<sup>150</sup> Although some significant limitations remain<sup>151</sup> and the measures must still comply with EU law, nonetheless the Member States have increased flexibility regarding the proportionality of the measures in particular. This is further complemented by Article 26b(3) also providing for opt-outs to avoid admixture.

This renewed flexibility regarding coexistence measures provides significant powers to the Member States – whether considered 'core' or 'complementary' – appropriate in light of the nature of GM cultivation. Unfortunately, regions are once again dependent upon their States to notify and support any coexistence measures, despite the Commission expressly noting that coexistence measures may need to be developed at a regional or local level.<sup>152</sup> Further, Article 26a also emphasizes the significance of coordination and communication in particular between areas/levels with distinct approaches to GM crops. Without this, even coexistence in the short term may prove fanciful. This however appears to be lacking in a structured and comprehensive fashion.

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<sup>145</sup> M Lee, 'The Governance of Coexistence Between GMOs and Other Forms of Agriculture: A Purely Economic Issue?' (2008) 20:2 JEL 193, 196-9.

<sup>146</sup> [2003] OJ L189/36.

<sup>147</sup> Article 4, Regulation 1830/2003, exempts produce from GM labelling requirements where the presence of authorised GMOs is adventitious and technically unavoidable and below the threshold (currently 0.9%).

<sup>148</sup> E.g. SEC(2006) 313.

<sup>149</sup> 2010 Co-existence Recommendation, Guidelines, Section 2.4.

<sup>150</sup> Case C-36/11 *Pioneer Hi Bred Italia Srl v Ministero delle Politiche agricole alimentari e forestali* (judgment of 6 September 2012, *nyr*), [75].

<sup>151</sup> E.g. If no alternative agri-type exists that could be affected by admixture, then restrictive measures are not warranted under Article 26a. Further, exclusion zones under Article 26a to protect consumer/producer choice could potentially breach Article XI GATT without being justifiable under Article XX: Dobbs (n138), Section 5.

<sup>152</sup> 2010 Co-existence Recommendation, Guidelines, Section 1.3.



To achieve a coherent approach, (i) information regarding the potential usefulness of coexistence measures in theory and practice would need to be available and shared with all levels; (ii) information regarding local conditions, farming practices, agri-types cultivated and coexistence measures developed across the EU would need to be shared; and (iii) some minimal harmonising principles or standards would need to be agreed in particular to manage cross-territorial issues including within Member States. The first is fulfilled to an extent by three EU research projects (now concluded) and the European Coexistence Bureau (2008 onwards), which have conducted important (centralised) scientific research regarding coexistence.<sup>153</sup> Although quite theoretical due to minimal EU GM cultivation, this research is crucial, with the Bureau providing non-binding technical reference documents that can assist multilevel decision-making. However, whilst the Bureau's mandate includes 'contributing towards preventing cross-border problems',<sup>154</sup> it does not deal with general concepts such as cross-territorial obligations and liability as beyond its current mandate and scope.<sup>155</sup> The second is fulfilled to an extent through the reports gathered on coexistence measures and registers of GM cultivation, but only some components are included. In addition, whilst COEX-NET facilitates further communication of information between the Member States, it omits key actors at the lower levels and only plays an informal role. The third is fulfilled to an extent via the Coexistence Recommendation, but it is scanty on general principles and the permissive nature of Article 26a means that Member States need not create any coexistence measures and undermines any attempt to establish a general framework of measures. Whilst Directive 2015/412 imposes a new obligation upon Member States to create cross-border measures by April 2017, this does not encompass internal measures even where regions take distinct approaches. Consequently, whilst Article 26a highlights the need for coherency and has the potential to facilitate it, it currently does not ensure it.

#### ***Article 26's support of Multilevel Governance?***

Overall, Article 26 decentralises significant powers to the national level whilst retaining some EU control, which reflects the nature of GM cultivation and the application of subsidiarity to an extent. However, the regional role is not guaranteed and there is a significant lack of coherency. The adoption of Article 26b heightens the challenge and urgency of the situation, as GM cultivation will likely increase within the EU and concurrently some territories will aim to be GM-free. Some coordination is required if Articles 26a and 26b are to have any long-term practical value.

In order to improve vertical and horizontal coordination and communication, a number of steps could be taken. The initial change would be to require the creation of coexistence measures, even if to merely indicate that the existing national law will apply and how. This would have to encompass internal measures also, rather than just cross-border measures. Where Member States (or regions) do not create coexistence measures, then it might be necessary to impose default coexistence measures. The second change would be to develop a loose coordinating framework or set of

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<sup>153</sup> MR Grossman, 'Coexistence of Genetically Modified, Conventional and Organic Crops in the European Union: The Community Framework' in Bodiguel and Cardwell (n12), 138-40.

<sup>154</sup> Mandate of European Coexistence Bureau as of May 2012: [http://ecob.jrc.ec.europa.eu/documents/MandateofECob\\_001.pdf](http://ecob.jrc.ec.europa.eu/documents/MandateofECob_001.pdf), 2.

<sup>155</sup> M Czarnak-Klos and E Rodríguez-Cerezo, *Best practice documents for coexistence of genetically modified crops with conventional and organic farming: 1. Maize crop production*, (2010) European Coexistence Bureau, JRC, IPTS, 45.

principles for the interaction of approaches between regions, internally within the Member States and between the Member States – essentially a coexistence framework for the entirety of the EU that would respect the choices made at the lower levels. This would reflect but also go beyond the current Guidelines, to set down general principles for instance regarding: protection of existing agri-types (whether GM or non-GM) generally; (non-)provision of compensation for producers who are detrimentally affected due to GM cultivation, coexistence measures or application of Article 26b; obligations to avoid cross-border admixture; and appropriate protection of official GM-Free locations following application of Article 26b.

The third change would be to improve communication vertically and horizontally to ensure that all relevant bodies and levels are suitably informed. To this end COEX-NET's role could be developed, with future interaction involving those at regional and local levels also. This would facilitate both the gathering and sharing of valuable information in developing, amending and implementing measures as appropriate. As well as facilitating the respect of various approaches at lower levels or in neighbouring regions in an efficient manner, through ensuring that no conflicting or unnecessary measures were taken, it would also allow for the sharing of practical experiences and knowledge. This would work in conjunction with the existing system that requires monitoring and traceability of GM crops.

Whilst these changes might seem like an intrusion into Member State competence, it would only be minimum harmonisation. The first is merely an extension of the obligation imposed by Directive 2015/412 regarding the creation of measures to address cross-border admixture. Whilst the creation of default coexistence measures would be significant, they would only apply where the Member States had failed to act and therefore continues to reflect the concept of subsidiarity. The second could be achieved *via* soft law and would simply be a revised form of the Coexistence Guidelines – ones that reflect the impact that Article 26b and future authorisations will have on the regime and the need for cohesion. Similarly extending the role of COEX-NET and the nature of the participants involved would be difficult to object to in light of its non-binding nature.

Consequently, Article 26a adds further powers to those granted to the Member States under Article 26b and also provides for a system that could, if adapted appropriately, facilitate the necessary communication and coordination. In order to achieve a system based on a more effective version of subsidiarity-based multilevel governance regarding aspects other than environmental or human health protection, it would seem that Article 26a merely requires some further depth and bolstering. However, this ignores the serious challenges regarding the role of the regions.

#### **4.3 Further consideration of the regions?**

As noted above, subsidiarity-based multilevel governance supports providing the lower levels (encompassing all relevant regions) with powers mirroring those advocated above for the Member States. Yet, a significant issue that crops up repeatedly is the subordinate position of the regions within the EU regime. Although there are key roles that individual regions could, and occasionally do, play in this

context,<sup>156</sup> the EU does little to enable this. Further, whilst the Conference of European Regions with Legislative Power (REGLEG) and the Committee of the Regions have important and growing roles, this does not suffice where it is the very heterogeneity of the issue and territories that has called for regional powers.<sup>157</sup> Instead, the regions remain in a precarious position, predominately reliant upon their Member States to support them at the EU level, e.g. through notifying safeguard measures or requesting opt-outs.

Whilst regions may be adequately represented by their Member State, a region may wish to develop a policy that conflicts with national policy or just is not strongly supported by them. Dialogue may prove effective, due to the consequences of the internal political fall-out or potential legal action against the State for breach of EU law due to regional measures. However, the relationship between them may be such as the regions will pay for any breaches (as in the UK), the State may decide that it is worth the risk to maintain their own national policy irrespective of regional policy or to use it as a strong negotiating tool to gather regional concessions (even where the region has internal competence for these matters), or the context might just mean that the State does not act in time (e.g. to opt-out before authorised crops are planted and therefore cannot be uprooted). Consequently, to achieve effective subsidiarity-based multilevel governance, the role of the regions needs significant bolstering – within the Member States and at the EU level.

To achieve this, a potential solution might be to include reference to regions within the relevant EU provisions. Clearly, this would still require varying degrees of controls over the use of powers and steps to ensure coherency – increasingly important with the further decentralisation of powers. Thus, regions might be permitted to create coexistence measures or request opt-outs, whilst leaving the overall/residual powers to the Member States so that they can create a national policy that facilitates regional action within it and, where the regions have not acted, provides for the general policy to encompass the regions also. Similarly, the regions could take safeguard measures, but with the same controls in place as for Member States. However, even more so than with the Member States, allocating relevant powers to the appropriate subnational bodies is not a simple issue, as for example it also asks what nature of regions should have policy-making powers and whether the EU can and should step in to support them.

Any transfer of powers is always challenging, but this is a relationship traditionally governed by the Member States and regions together. Whilst the EU generally is accepting of further delegation of powers within Member States, provided that EU law is still complied with,<sup>158</sup> it is an entirely different matter to attempt to carry out this delegation itself or alternatively require Member States to do so. This is arguably a significant interference with national governance and State competence to determine the division of relevant legislative powers internally.<sup>159</sup> Indeed, despite internal pressures from the various regions, Committee of Regions, Parliament and REGLEG, as noted above, the Commission and Council avoided providing the regions with

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<sup>156</sup> Hunt (n142).

<sup>157</sup> Weatherill (n22), 19-25.

<sup>158</sup> Case 227/85 *Commission v Belgium* [1988] ECR 1.

<sup>159</sup> J Hunt, 'Ploughing their own furrow: subnational regions and the regulation of GM crop cultivation' (2012) 13 CYELS 135, 159; and Weatherill (n22), 2-3.

express powers in Article 26b or a substantively strengthened role more generally. For instance, whilst the Lisbon Treaty provides national parliaments with a role in ensuring compliance with subsidiarity and proportionality,<sup>160</sup> it is up to the national parliaments to include regional parliaments ‘where appropriate’.<sup>161</sup>

Yet EU measures to support the regions would not necessarily involve interfering directly in the internal relationships and national division of powers and responsibilities. The EU could simply adjust its legislation to facilitate subnational regions that hold relevant powers within their nation-state to act in the EU context also - akin to the Commission’s propositions in its White Paper on Governance.<sup>162</sup> Alternatively, the EU could require Member States to involve competent regional or other bodies, as done in the case of partnership agreements regarding Cohesion policy for instance.<sup>163</sup> In both of these examples, the EU expressly notes that such approaches are to be in accordance with the existing national constitutional and administrative arrangements; arguably such changes would merely prevent the EU undermining the existing roles of regions nationally and thereby would be ‘leaving them alone’.<sup>164</sup>

However, it should be noted that there are serious limitations with these proposals, besides achieving the political agreement to make the reforms! With the former, firstly, non-legislative regional bodies would still be left to negotiate as normal with their Member States. Secondly, it would also leave the contradiction whereby legislative regions wishing to impose restrictions might be able to act according to their own policies, but those wishing to cultivate GM crops in contrast with their Member State wishing to be GM-free nationally would still be reliant upon their State to respect their wishes in narrowing the geographical scope of any Article 26b application. If the region were to be able practically to cultivate relevant GM crops without undermining the Member State’s ability to remain GM-free elsewhere, it would seem logical that they should hold the powers to make such a decision – with coordination then between the regions and with the Member State to promote coexistence as best possible. With the latter, the regions would be unlikely to have a determinative say in the final decisions. Nonetheless, whilst not ideal from the perspective of subsidiarity-based multilevel governance, either option would at least be a step in the right direction.

## CONCLUSION

This article aimed to outline a potential normative framework for determining where to allocate policy-making powers regarding GM cultivation in the EU context, in the form of subsidiarity-based multilevel governance. It also aimed to analyse the nature and extent of the main controls left to Member States and subnational regions regarding GM cultivation post-authorisation in light of this framework. As noted above, whether these mechanisms currently fulfil the criteria effectively depends in particular on whether the core powers are located at the appropriate level(s), complementary powers are located at the other levels and relevant coordination exists

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<sup>160</sup> Articles 5(3) and 12(b) TEU.

<sup>161</sup> Article 6, Protocol No.2 on Subsidiarity and Proportionality. Cf. Jeffrey, ‘Regions and the European Union: Letting them in, and Leaving them Alone’ in Weatherill and Bernitz (n22), 40-1.

<sup>162</sup> COM(2001)428, 9.

<sup>163</sup> Article 5, Regulation (EU) No 1303/2013, [2013] OJ L347/320.

<sup>164</sup> Jeffrey (n161), at 37-8.

both vertically and horizontally to ensure broad coherency across and throughout the levels (without necessarily amounting to harmonisation of policy content or implementation measures).

The EU GM cultivation regime presents an apparently haphazard and contradictory approach, with continued harmonisation of some elements (authorisation and safeguard measures) and softer harmonisation of others (coexistence measures initially), but with significant and extremely unusual elements of de-harmonisation also (later approach to coexistence measures and Article 26b). Yet upon closer examination a pattern emerges, which distinguishes between environmental and health protection on the one hand and other legitimate objectives on the other.

The combination of pressures within this contentious area has led to a division of powers within the EU. The EU has fortified its hold over the core powers regarding health and environmental risks, in principle at least. However, the EU has increasingly decentralised post-authorisation powers regarding other legitimate objectives – thereby enabling national restrictions. As this article argues that the appropriate level is the EU for the former powers and the Member States and regions for the latter powers, this approach would appear to indicate a clear, gradual move towards effective operation of subsidiarity-based multilevel governance.

However, the discussion above also demonstrates that the evaluation is not so clear-cut, even following Article 26b's enactment. Firstly, the regions still play a subordinate role even where they should hold some relevant powers. Secondly, the existence of an appropriate level for the core powers does not mean that other levels should not have complementary powers related to the same issue or objective also – powers that are lacking regarding environmental and health risks especially. Thirdly, the provision of relevant powers at the appropriate levels needs to be balanced with the coordination and cohesion of policy and this is yet to be achieved satisfactorily – this is extremely important considering the nature of agriculture and the environment, the challenges for coexistence and the potential expansion of GM cultivation in some parts of the EU in the future. Consequently, to achieve effective subsidiarity-based multilevel governance in light of the above analysis, further (contentious) steps are required.

In conclusion, it should be recalled that subsidiarity-based multilevel governance will not act as a panacea for the governance of GM crops, whether within the EU or beyond – the area is too contentious and too complicated due to the very nature of GM cultivation. Further, the discussion above is naturally limited in scope, e.g. regarding the range of issues/interests covered and the depth of the examination, and others may well argue that the concept should apply differently. In particular, further in-depth investigation will be needed regarding how the Member States, regions and indeed producers react to the opportunities and challenges that now face them in light of Article 26b and the likelihood of future authorisations<sup>165</sup> – as highlighted by the conflict within Germany over whether the Länder or the Federal State should implement Article 26b.<sup>166</sup> However, it is hoped that this discussion will challenge

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<sup>165</sup> M Dobbs, 'GM crops: an uneasy truce hangs over Europe', The Conversation (UK), 8 October 2015, <https://theconversation.com/gm-crops-an-uneasy-truce-hangs-over-europe-48835>.

<sup>166</sup> D Tost, 'German government quarrels over GMO cultivation ban', 19 March 2015, <http://www.euractiv.com/sections/agriculture-food/german-government-quarrels-over-gmo-cultivation-ban-313037>.



others to consider proactively where and how the powers ought to be divvied up across the levels and provides a focus point for that debate.

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